Use of sirolimus-coated balloon in de novo small vessel coronary lesions; Long-term follow-up from a single centre registry

B.H. Loku Waduge, H. Kalkat, A. Saif, A.M. Fawzy, S. Athukorala, G. Bhatia, N. Kumar, B. Freestone, J. Ment, K. Lee, M. Pitt, G. Pulikal, S. Basavarajaiah

Birmingham Heartlands Hospital, Birmingham, United Kingdom
Funding Acknowledgement: Type of funding sources: None.

Background: Drug coated balloons (DCBs) in Europe are mainly used in restenotic lesions as endorsed by the European Society of Cardiology, with a class IA recommendation. However, some of the recent data suggest, it can also be considered in a subset of denovo lesions, especially in small vessels. Most DCBs used, are coated with Paclitaxcel. There is no data on the efficacy of Sirolimus in DCBs, the drug of choice in drug eluting stents. In this study, we report outcomes from the use of a Sirolimus coated balloon (SCB) in de novo small-vessel coronary lesions, from a single high yield centre.

Methods: A retrospective analysis was conducted on all patients treated with an SCB between March 2018 and October 2020. Follow-up was achieved with clinic visits, telephone calls and admission records. The outcomes measured include cardiac death, target-vessel myocardial-infarction (TVMI), target lesion revascularisation (TLR) and MACE (combination of cardiac death, target-vessel MI and TLR).

Results: During the study period, 279-patients (with 332-lesions) with de novo lesions were treated with an SCB. The mean age of patients was 65±12 years, 219 (79%) were male, 36% (n=100) had diabetes, 16% (n=45) had chronic kidney disease and 61% were in the setting of acute coronary syndrome (n=169). Predilatation was performed in 96% (320-lesions). Bailout stenting (with DES) was required in 5% of lesions (n=18) of which 16 were due to dissections and 2 were due to recoil >30% following DCB use. The mean diameter and length of DCBs were 2.35 mm and 26 mm respectively.

During a median follow-up of 584-days (19-months) cardiac death was reported in 8 patients (3%). Target vessel MI was in 3% (n=9), TLR per lesion was 8% (n=26) and the MACE rate was 11% (n=31). There were no documented cases of acute vessel closure.

Conclusion: The long-term outcome from the first ever study on sirolimus eluting balloons in de novo small vessel lesions appears promising with low rates of hard endpoints, and acceptable repeat rates of TLR despite a complex group of patients (50% ACS, 36% diabetics and 19% CKD) and lesion subsets (small vessel and diffuse disease). Implanting stents in these subsets renders them vulnerable to restenosis, making treatment challenging and resulting in high rates of recurrence.